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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Jan Andrianus VERSCHOOR, et al

Serial No.: 09/696,605 Group No.: 1614

Filed: October 25, 2000 Examiner: K. Weddington

For: COMPOSITION COMPRISING A CARRIER AND A PURIFIED MYCOBACTERIAL LIPID CELL-WALL COMPONENT AND ITS USE IN THE PREVENTION, TREATMENT AND DIAGNOSIS OF DISEASE

Bet
3-23-02

Attorney Docket No.: U-013022-9

Assistant Commissioner Patents and Trademarks
Washington, DC 20231

RESPONSE TO OFFICIAL ACTION

Sir:

The Official Action of 5 October 2001 has been carefully considered and reconsideration of the application in view of the present submission is respectfully requested.

Claims 59 to 64 stand rejected under 35 USC 102 (b) as allegedly being anticipated by Verschoor et al (WO 9528642). Applicants respectfully traverse this rejection.

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, DC 20231

CLIFFORD J. MASS
Type or print name of person mailing paper)

Date: March 5, 2002

(Signature of person mailing paper)

The invention as claimed is directed to a method for diagnosing a mycobacterial infection by detecting **antibodies** in a sample from a subject that react with a purified mycobacterial antigen. The claimed invention is based upon the applicants' findings that mycolic acids are immunogenic in respect of being able to induce antibodies that react with purified mycolic acids. This is shown, for example, in Example 3 on pages 158-189 of the specification, which describes the detection of anti-mycolic acids antibodies in patients' sera by contacting this sera with mycolid acids and detecting reactions. The screening of patient samples to detect the presence in the samples of **antibodies** to mycolic acids is described, for example, in the specification at pages 178-180, pages 185-186 and Figures 29 and 30 of the drawings.

By contrast, the cited reference describes a method to detect the presence of tuberculosis **antigens** in a patient. So, for example, the reference describes a method wherein a mycobacterial antigen in a biological sample from the patient is detected by exposing the sample to an antibody specific for the mycobacterial antigen (see, for example, claim 2 of the reference). The reference does not show or suggest the detection of **antibodies** in the patient's sample.

The detection of antibodies rather than antigens in a patient's sera provides a number of advantages for the diagnosis of tuberculosis "TB", including:

The detection of anti-TB antibodies in patients as surrogate marker for infection is a more feasible way to diagnose tuberculosis than attempting to detect the presence of the TB antigen in body fluids and tissues. The TB pathogen is a slow growing organism with the ability to lie dormant in an infected patient, making its direct detection difficult, if not impossible under certain circumstances. The presence of antibodies to the TB pathogen, on the other hand,

indicate that the patient has been or is exposed to tuberculosis, even for a significant length of time after the pathogen itself has gone into the dormant state. This reduces the frequency of false negative results.

Antibodies against lipid antigens can be expected not to be affected by co-infection with the Human Immunodeficiency Virus (HIV), contrary to the more common situation of protein antigens. This is because the lipid antigens cannot make use of the helper T lymphocytes to produce antibodies, as the protein antigens do. It is exactly the helper T lymphocytes responding to protein antigens which are paralyzed by the HIV-virus. So many TB patients, especially in Africa, are now co-infected with HIV (>70 %) that this is increasingly becoming a problem.

Antibodies to the TB antigen are more abundant in the body than TB antigens. One may expect up to 4 g of specific anti-TB antibodies in a human TB patient, while very little antigen may be detectable, especially after commencement of chemotherapy. The probability of detecting specific anti-TB antibodies is therefore considerably higher than the probability of detecting the TB antigen. This allows for increased sensitivity in a diagnostic test that aims at detecting specific antibodies, rather than the direct determination of TB antigen.

In view of the above, the claimed invention is believed to be patentably distinguishable from the cited reference and the application is believed to be in allowable form. An early notice

of allowability is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,

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1614

Practitioner's Docket U-013022-9

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Attorney Docket No.: U-013022-9

Assistant Commissioner for Patents
Washington, DC 20231

AMENDMENT TRANSMITTAL

1. Transmitted herewith is an amendment for this application.

STATUS

2. Applicant is

- ☐ a small entity. A statement:
  - ☐ is attached.
  - ☐ was already filed.
- ☒ other than a small entity.

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231.

FACSIMILE

☐ transmitted by facsimile to the Patent and Trademark Office.

Date: March 5, 2002

Signature

CLIFFORD J. MASS
(type or print name of person certifying)

EXTENSION OF TERM

NOTE: "Extension of Time in Patent Cases (Supplement Amendments) — If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.

If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of December 10, 1985 (1061 O.G. 34-35).

NOTE: See 37 CFR 1.645 for extensions of time in interference proceedings, and 37 CFR 1.550(c) for extensions of time in reexamination proceedings.

3. The proceedings herein are for a patent application and the provisions of 37 CFR 1.136 apply.

(complete (a) or (b), as applicable)

(a) ☒ Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)(1)-(4)) for the total number of months checked below:

	Extension (months)	Fee for other than small entity	Fee for small entity
☐	one month	$ 110.00	$ 55.00
☒	two months	$ 400.00	$ 200.00
☐	three months	$ 920.00	$ 460.00
☐	four months	$ 1,440.00	$ 720.00

Fee: $400.00

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

☐ An extension for _____ months has already been secured. The fee paid therefor of $ _____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request $ _____

OR

(b) ☐ Applicant believes that no extension of term is required. However, this is a conditional petition being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.

FEE FOR CLAIMS

4. The fee for claims (37 CFR 1.16(b)-(d)) has been calculated as shown below:

	(Col.1) Claims Remaining After Amendment		(Col. 2) Highest No. Previously Paid For	(Col. 3) Present Extra	SMALL ENTITY Rate	Addit. Fee	*OR*	OTHER THAN A SMALL ENTITY Rate	Addit. Fee
Total	*	Minus	**	=	x $ 9 =	$		x $18 =	$
Indep.	*	Minus	***	=	x $42 =	$		x $84 =	$
[ ] First Presentation of Multiple Dependent Claim					+ $140 =	$		+ $280 =	$
					Total Addit. Fee	$___	*OR*	Total Addit. Fee	$___

* If the entry in Col. 1 is less than the entry in Col. 2, write "O" in Col. 3,
** If the "Highest No. Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest No. Previously Paid For" (Total or Indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

WARNING: *"After final rejection or action (§ 1.113) amendments may be made canceling claims or complying with any requirement of form which has been made." 37 CFR 1.116(a) (emphasis added).*

(complete (c) or (d), as applicable)

(c) ☐ No additional fee for claims is required.

OR

(d) ☐ Total additional fee for claims required $ _____.

FEE PAYMENT

5. ☒ Attached is a check in the sum of $400.00 .

☐ Charge Account No. 12-0425 the sum of $ _____.
A duplicate of this transmittal is attached.

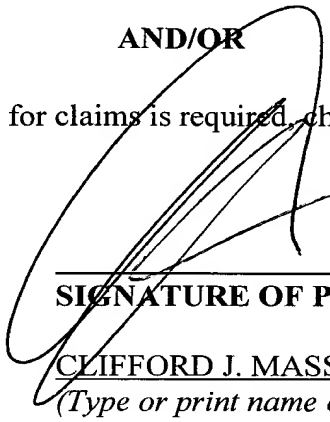
FEE DEFICIENCY

NOTE: *If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO Finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, (1065 O.G. 31-33).*

6. ☒ If any additional extension and/or fee is required, charge Account No. 12-0425.

AND/OR

☒ If any additional fee for claims is required, charge Account No. 12-0425



SIGNATURE OF PRACTITIONER

Reg. No. 30,086

CLIFFORD J. MASS
(Type or print name of practitioner)

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